UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	**Criminal No.: 08-CR-10338-WGY**
v.	
DARNELL MARTIN,	
Defendant.	

AGREED STATEMENT OF FACTS

The United States of America, by and through its counsel, and defendant Darnell Martin, individually and by and through his counsel, respectfully submit the following agreed statement of facts in connection with the plea hearing in United States v. Darnell Martin, 08-CR-10338-WGY. Mr. Martin acknowledges that the following is a true account of his conduct in connection with the crimes charged in the Information.

From August 2004 through early November 2007, Mr. Martin was employed in a sales capacity, first as a territory manager and for the last few months as a regional manager, by a corporation based in Hopkinton, Massachusetts, and referred to in the Information as XYZ Corporation, that manufactured and sold certain medical devices, including medical devices for use in healing of fractured or broken bones. These medical devices included the following: (a) a device, referred to herein as Device-A, which was an implant to promote growth in certain long bone non-unions; a device, referred to herein as Device-B, which was a putty to promote bone growth in certain spinal fusions; and (c) a device, referred to herein, as Device-C, which was a bone void filler for surgically created osseous defects or osseous defects resulting from traumatic

injury.

Each of Device-A, Device-B and Device C was a medical device within the meaning of the Federal Food, Drug and Cosmetic Act, and as such was regulated by the United States Food & Drug Administration ("FDA"). In response to prior applications submitted to the FDA by XYZ, by mid-2004, the FDA had approved each of Device-A and Device-B pursuant to a Humanitarian Device Exemption. The FDA approval for Device-A was only for "use as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed." The FDA approval for Device-B was only for "use as an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion."

Also, in mid-2004, the FDA, in response to XYZ's premarket notification of intent to market a bone void filler product, notified XYZ that it could market the device, referred to herein as Device-C, as indicated as "a bone filler for voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated for surgically created osseous defects or osseous defects resulting from traumatic injury."

Humanitarian Device Exemptions, sometimes known as HDEs, are among the narrowest form of FDA approvals and impose a number of restrictions on the holder of the HDE. For starters, HDEs are for medical devices designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States. The holder of an HDE is prohibited from selling the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device. Also, by statute, HDEs may only be used in facilities

that have established a local institutional review board, known as an IRB, which must approve the device before its use.

Absent an emergency situation in which an IRB approval could not be obtained in time to prevent serious harm or death to a patient, in order for XYZ to ship Device-A or Device-B to a medical facility, and in turn to bill that facility for the medical devices, XYZ had to have an approval from an IRB approving the labeled use of the device at the relevant medical facility. XYZ gave its sales force, including Mr. Martin, the responsibility for obtaining IRB approvals, and sometimes motivated the sales force with bonuses for obtaining a certain number of IRB approvals over a particular period of time.

On or about May 18, 2007, Mr. Martin falsified an IRB approval. This IRB approval purported to be on behalf of an IRB for a medical facility in Wisconsin and purported to approve use at the Wisconsin medical facility of Device-A for the period May 16, 2007 through May 16, 2008. This IRB approval purported to be signed by the Chair of the IRB Committee. Mr. Martin prepared this false IRB approval, which was not actually signed by the IRB Committee chair. Mr. Martin then provided this false IRB approval to XYZ in Hopkinton, Massachusetts, and in turn XYZ shipped Device-A and billed Device-A to the Wisconsin medical facility. These IRB approvals were mandated by the FDA and subject to review and audit by the FDA and as such were statements in a matter within the jurisdiction of the FDA, part of the executive branch of the United States Government.

After learning that one of his colleagues had been terminated by XYZ for falsifying IRB approvals in another region of the country, Mr. Martin sent an e-mail to XYZ in Hopkinton, Massachusetts in which he purported to forward an e-mail from the IRB representative from the

Wisconsin medical facility claiming that the Wisconsin medical facility had canceled its previous IRB approval for Device-A. The forwarded e-mail was fabricated by Mr. Martin in an effort to keep his job by avoiding detection of his IRB falsification. Both in this e-mail, and in the false IRB approval, Mr. Martin abused the authority of his position by using without authority the names of specific individuals.

Based on Mr. Martin's false IRB approval, XYZ made a number of shipments of Device-A to the Wisconsin medical facility. Device-A had a cost of $5,000 per unit. Mr. Martin also falsified other IRB approvals for Device-A, some with respect to certain other medical facilities, and sent them to XYZ in Hopkinton, Massachusetts. The falsified IRB approvals for the Wisconsin medical facility and other medical facilities resulted in 26 deliveries of Device-A. Mr. Martin's conduct in falsifying IRB approvals resulted in a loss of $130,000, as none of those devices should have been shipped, billed for or used.

XYZ has never applied to the FDA for use of Device-B in conjunction with or mixed with Device-C, nor has the FDA ever approved any such use. From approximately April 2006 through at least March 2007, Mr. Martin and others at XYZ promoted the sale and use of Device-B to be mixed with and used in conjunction with Device-C. This was an unapproved use.

One of the means by which Mr. Martin and others at XYZ promoted this unapproved use was to prepare and/or distribute to others (including surgeons, surgical staff, XYZ colleagues, or employees of XYZ affiliates) "mixing instructions." There were a variety of mixing instructions used by Mr. Martin and XYZ. One set used by Mr. Martin in March 2007 directed the user to "[e]mpty both of the [Device-B vials] into a specimen container." The mixing instructions then directed the user to "[a]dd 2.5 cc of saline (or the patient's blood) Stir." Then the instructions

directed to "[a]dd the contents of [Device-C] into the container." Finally, the instructions said to "[a]dd an additional 3cc of saline (or the patient's blood) to the specimen container. Mix the contents." These mixing instruction documents constituted labeling of the two products, and the labeling was false or misleading because neither Device-B nor Device-C was approved by the FDA for combined use.

Mr. Martin's conduct caused the introduction into interstate commerce of a misbranded device, namely Device-B. Mr. Martin acted with an intent to defraud or mislead in that prior to March 2007, he was aware that neither Device-B nor Device-C was approved by the FDA for combined use. Mr. Martin was also aware that he was prohibited from providing written mixing instructions for combined use of Device-B and Device-C and took steps to try to make sure that his instructions were kept "confidential" by certain recipients of the mixing instructions. Mr. Martin had been made aware through training and other sources of reports of adverse events in some patients in whom a mixture of Device-B and Device-C had been implanted.

Based on these facts and evidence, which are only a portion of that which would be offered at trial, the United States would be able to prove beyond a reasonable doubt each of the elements of a violation of 18 U.S.C. §1001 and a violation of 21 U.S.C. §§331(a) and 333(a)(2) as charged in the Information.

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